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**SEIRIN-America, Inc.**  
230 Libbey Parkway  
Weymouth, MA 02189

fax: 617-335-5779  
phone: (617) 340-1827

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**PRE-MARKET NOTIFICATION 510(k) SUMMARY**

(As Required by 21 CFR 807.93)

**Intended Use.** Pyonex acupuncture needles are (defined as) devices intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

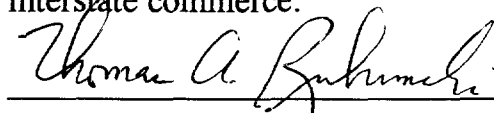
Acupuncture needles have been used for the general practice of acupuncture in the United States for over 30 years. Since this time, we are not aware of any serious or life threatening accidents involving acupuncture needles.

Acupuncture needles which were sold through commercial interstate distribution prior to May 28, 1976 were non-sterile, reusable acupuncture needles. Acupuncture needles which are currently being marketed through interstate distribution (ie, 1996) offer greater safety since they are sterile, single use only acupuncture needles.

The subject of this 510(k) application - the Seirin PYONEX Acupuncture Needle - is a sterile, single use only acupuncture needle. The Seirin PYONEX Acupuncture Needle meets the general specifications and criteria for an acupuncture needle and is effective for the practice of acupuncture.

The Seirin PYONEX brand acupuncture needle was first manufactured in Japan in 1978 and has been imported and sold through interstate commerce in the USA since 1983 under the FDA labeling restrictions of: "Caution: Investigational device limited by U.S. law to investigational use". Since 1983, no accidents or device failure claims have been reported as a result of using the Seirin PYONEX brand acupuncture needle.

In conclusion, based on the information provided with this 510(k) application, the Seirin PYONEX Acupuncture Needle meets the criteria for 510(k) acceptance. The Seirin PYONEX needle is equivalent to acupuncture needles which were in commercial distribution prior to May 28, 1976. Also, the Seirin PYONEX needle is equivalent to other acupuncture needles which are currently being sold through interstate commerce.

  
Thomas A. Riihimaki, President

2/4/97

Date

page 7